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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,970	09/18/2000	Rainier Betelia	249/056	4613
34313	7590	12/02/2004	EXAMINER	
ORRICK, HERRINGTON & SUTCLIFFE, LLP			HO, UYEN T	
4 PARK PLAZA			ART UNIT	
SUITE 1600			PAPER NUMBER	
IRVINE, CA 92614-2558			3731	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/664,970	BETELIA ET AL.	
	Examiner	Art Unit	
	(Jackie) Tan-Uyen T. Ho	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-20,37 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 10-20,37 and 39 is/are allowed.
- 6) ☒ Claim(s) 1 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/06/2002</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 8/9/04 have been fully considered but they are not persuasive. In response to applicant's argument that the claim language "the leaflets being deflectable, without exposure to a softening liquid" structurally distinguishes the claims from Cox in view of Martinez, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The "leaflets" between the weakened area or slits of Martinez reference are deflectable without exposure to softening liquid if one desired to do so by distally advancing the inner components (12) of the sheath until breaking the weakened area or breaking the weakened area by other means instead of softening liquid.

2. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

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Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, in the knowledge generally available to one of ordinary skill in the art such that one looks at Martinez reference which teaches the smooth rounded atraumatic tip (col. 5, lines 8-10), would prefer the smooth rounded tip as disclosed by Martinez for his/her delivery sheath to prevent trauma.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox '758 in view of Martinez et al. '909. Cox discloses all the limitations of the claims including a bumper (26). However, Cox fails to disclose weakened regions between slits/leaflets. Martinez et al. disclose a implant delivery system including an elongate tubular outer sheath having a distal end configured to prevent trauma when inserted into a vessel, the distal end including a plurality of flexible leaflets being deflectable from a closed position to an open configuration and the leaflets are connected to one another by weakened regions and the weakened regions being tearable for deploying an implant (col. 4, lines 6-64). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ weakened regions between the plurality of flexible slits/leaflets of Cox's sheath in order to prevent the leaflets from

flaring out and damaging the wall of a blood vessel during advancing Cox's delivery system into a vessel.

The introductory statement of intended use and all other functional statements for example "without exposure to a softening liquid" have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the device of Cox in view of Martinez which is capable of being used as claimed if one desires to do so.

Allowable Subject Matter

5. In regard to claims 10-20, 37 and 39, Applicant's arguments filed 2/13/04 have been fully considered persuasive. Therefore claims 10-20,37 and 39 are allowed.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731

November 16, 2004


ANHTUAN T. NGUYEN
PRIMARY EXAMINER

11/23/04